

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) 110129.411
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____.	Application Number  09/476,490	Filed  December 30, 1999
Signature _____  Typed or printed name _____	First Named Inventor Lindsay S. Machan	
	Art Unit 3731	Examiner Tan-Uyen T. Ho
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).            Note: No more than five (5) pages may be provided.</p> <div style="margin-top: 20px;"> <p>I am the</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest.            See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.            (Form PTO/SB/96.)</p> <p><input checked="" type="checkbox"/> attorney or agent of record.            Registration No. <u>51,017</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.            Registration number if acting under 37 CFR 1.34 _____.</p> </div> <div style="width: 35%; text-align: right;"> <p>_____ /David L. Enfield/ Signature</p> <p>_____ David L. Enfield, Ph.D. Typed or Printed Name</p> <p>_____ (206) 622-4900 Telephone Number</p> <p>_____ March 5, 2008 Date</p> </div> </div> </div>		
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.		
<input type="checkbox"/> *Total of _____ forms are submitted.		

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## PRE-APPEAL BRIEF REQUEST FOR REVIEW REMARKS

Claims 3 and 12-15 remain rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Wang (US Patent No. 6,379,379 ('379)). Claims 4 and 11 remain rejected as allegedly unpatentable over Wang ('379) under 35 U.S.C. § 103(a). Other than these, no previous grounds for rejection of Applicants' claimed invention have been maintained, all having been asserted in previous Actions as having been rendered moot in view of amendments made by Applicants to the claims, without prejudice, for the purpose of clarification or to expedite allowance. Accordingly, this Request for Review is directed only to the above rejections citing Wang ('379). Applicants respectfully request review of these grounds for rejection for the reasons discussed in detail below.

### ***Rejections under 35 U.S.C. § 102(e)***

Applicants respectfully submit that Wang ('379) fails to teach or describe each and every element of, and thus does not anticipate, Applicant's claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants' invention, as claimed in instant claim 3, and thus also in instant claims 4 and 11-15 depending therefrom, is a "stent graft, comprising an endoluminal stent and a graft, wherein said stent graft further comprises a vessel wall irritant and wherein, when implanted into a blood vessel, said stent graft induces or accelerates an *in vivo* fibrotic reaction at a tissue in the vicinity of said stent graft." Thus, Applicants' invention requires at least three elements: a stent, a graft, and a vessel wall irritant. Accordingly, to anticipate the instantly claimed invention, Wang must teach or disclose a device having at least all three of these elements. Applicants submit that Wang fails to teach, disclose, or even suggest two of the three required elements, namely, the graft and the vessel wall irritant. Applicants further submit that the Action has not provided adequate rationale for citing Wang as anticipating all three of these required elements. Wang teaches only a stent having a coating or a sleeve at one or both ends. As taught by Wang, the coating or sleeve is

designed to provide a smooth surface at one or both ends of the stent to prevent damage to the vessel wall, and thus formation and proliferation of scar tissue, which may occur upon insertion of an unmodified stent into a vessel. Wang further teaches that the coating or sleeve may include a bioadhesive to repair the tissue wall in the event of a tear or dissection.

Applicants strongly disagree with the assertion in the current Action, as simply reiterated from the previous Action, that “Wang discloses a stent graft comprising a stent (44) and a graft (46) ....” The Action attempts to further explain this assertion as follows:

Examiner’s position is that with a broadest reasonable interpretation, the sleeve (46) of Wang reference encompasses a graft function and it is considered to be a graft. The sleeve (46) is a tube that has a stent (44) to hold the sleeve open and permit attachment of the sleeve to a body passageway. The sleeve is (46) adapted to prevent the flow of fluids from the inside to the outside of the sleeve. The claimed limitations do not exclude a sleeve (46) placed on the stent (44) from being a graft and the claimed limitations do not limit the claim the stent graft as claimed to be used for bypassing a damaged body passageway.

Applicants submit that this explanation does not appear to accurately represent the structure or function of a stent graft or the disclosure of Wang. In particular, Applicants submit that the sleeve positioned at one or both ends of a stent, as disclosed by Wang, does not encompass the function of a graft in a stent graft. Applicants further submit that Wang does not describe or even suggest that the sleeve is a tube having a stent to hold it open and to permit its attachment to a body passageway. Applicants thus submit that the sleeve does not correspond to a graft and that Wang thus does not disclose a graft attached to the stent. In this regard, Applicants note that Wang ‘379 was cited in a previous Office Action dated May 18, 2005, as the basis in part for a rejection under 35 U.S.C. § 103(a). Applicants draw particular attention to page 3, item 4, of this previous Action, where it is explicitly admitted that “Wang does not disclose ... a graft attached to the stent.” Applicants further note that, although the claims have since been further limited by amendment, without prejudice, the claims as now pending are rejected under 35 U.S.C. § 102(e). Nevertheless, in view of the assertions in the current Action, Applicants wish to further clearly distinguish the stent taught by Wang as having a sleeve at one or both ends from the stent graft to which the currently pending claims are directed. Accordingly, Applicants submit in particular that a graft is a tubular structure that serves to transport fluid without flow or leakage of fluid through its walls. A stent is a tubular structure with walls made from an open material, such as a wire

mesh. Since fluid can freely flow through the open structure of the walls, a stent cannot serve to transport fluid. A stent graft is a graft, typically of a form in which some or all of the graft is associated with a stent. Certain forms of stent grafts may have short portions of the ends of the stent extending beyond the ends of the graft. However, there appear to be no stent grafts described in the art wherein the graft portions are associated only with one or both ends of the stent. Accordingly, since graft material forms at least most of the entire length of the structure of a stent graft, no flow or leakage of fluid occurs through the walls of the stent portion of the stent graft, except possibly at the very ends of the stent in cases wherein the ends extend beyond the ends of the graft. A stent graft, like a graft, can thus serve to transport fluid and is at least functionally primarily still a graft. A variety of commercially available stent grafts clearly demonstrate that such devices are structurally and functionally grafts having stents associated therewith, including, for example, the AneuRx AAA Advantage Stent Graft (<http://www.medtronic.com/physician/aneurx/index.html>); the Talent Thoracic Stent Graft System ([http://medgadget.com/archives/2007/03/talent\\_thoracic.html](http://medgadget.com/archives/2007/03/talent_thoracic.html)); and the FLAIR Endovascular Stent Graft (<http://www.fda.gov/cdrh/mda/docs/P060002.html>). Applicants submit that, in clear contrast, the stent of Wang, having sleeves at one or both ends, cannot serve to transport fluid through its length, but only possibly at the ends, where it is covered by a sleeve. Fluid will still freely flow through all other portions of the walls that are not covered by a sleeve. Accordingly, Applicants submit that a stent partially covered with a sleeve at one or both ends, even with the broadest reasonable interpretation, is not structurally or functionally equivalent to a stent graft, such as any of those commercially available, as identified above. To further clarify, it may be useful to consider a common exemplary use of a stent graft, such as to span and provide an alternative passageway for the flow of blood from one side to the other of a portion of a blood vessel having an aneurysm, wherein it is the tubular graft that transports blood through the passageway, with the stent portion simply holding the tubular graft open and against the inner surface of the vessel wall. The stent taught by Wang, having open mesh walls with a sleeve at one or both ends, would fail in this common application, or for that matter in any other application in which a stent graft may be used. Even if one were to very broadly interpret the disclosure of Wang to include sleeves at both ends of the stent long enough to meet in the central portion of the stent, the device would still allow flow, or at least leakage, of blood outward through the walls of

the stent at the junction of the two sleeves. Accordingly, Applicants respectfully submit that, consistent with the admission in the Action dated May 18, 2005, Wang clearly fails to teach, disclose, or even suggest, a stent graft.

Applicants further disagree with the assertion reiterated in the current Action that “Wang discloses a stent graft ... wherein the grafts include a vessel wall irritant.” Applicants submit that Wang does not in fact teach, disclose, or even suggest a device having a vessel wall irritant. As the basis for this rejection, the Action cites from Wang column 7, lines 5-21, and, presumably, although incompletely identified, column 8, lines 20-57. Wang discloses that a coating or sleeve applied to a stent may include a bioadhesive. Wang does not teach, disclose, or even suggest, nor does the Action provide any basis in the art or documentary evidence, that bioadhesives, in general, or any of those specifically disclosed in Wang are vessel wall irritants. Wang does not teach or discuss use of a bioadhesive or any other agent as an irritant to induce or accelerate an in vivo fibrotic reaction between a stent and tissue of a vessel wall in the vicinity of the stent. Accordingly, Wang fails to teach, disclose, or even suggest a vessel wall irritant or a device comprising a vessel wall irritant.

In summary, Applicants thus respectfully submit that Wang fails to disclose “a stent graft, comprising an endoluminal stent and a graft, wherein said stent graft further comprises a vessel wall irritant...,” as claimed in instant claim 3, and thus in claims 4 and 11-15.

#### ***Rejection under 35 U.S.C. § 103(a)***

Applicants respectfully submit that Wang ‘379 does not serve as the basis for an obviousness rejection of instantly pending claims 4 and 11. The Action asserts in item 5 at page 4 that “Wang discloses all the limitations of the claims except fails to disclose a stent-graft being bifurcated and the wall irritant being selected from the groups as listed in claim 4.” As discussed in detail above, Wang teaches a stent, but fails to teach or even suggest a graft or a vessel wall irritant, that is, two of the three required elements in claim 3, and thus claims 4 and 11. There is no further disclosure in Wang, nor is there any further rationale provided in the Action related to claims 4 and 11, to overcome these deficiencies in Wang. The Action asserts that “it would have been obvious to modify Wang’s stent having bifurcated configuration.....” However, providing a stent with a bifurcated configuration does not overcome the failure of Wang to teach a stent graft.

In fact, with a bifurcated stent, it is nearly impossible to envision inserting one or more ends of the stent into sleeve(s) as disclosed by Wang to form a non-leaking bifurcated alternative fluid passageway. The Action further asserts, regarding claim 4, that “it would have been obvious matter of design choice to use the bioadhesive materials as claimed for Wang’s stent graft ....” Recitation of the specific materials in claim 4 provides no basis to overcome the failure of Wang, as discussed above, to teach, disclose, or suggest, vessel wall irritants. The Action has simply asserted that the materials to which claim 4 is directed are bioadhesives without providing any basis in the art, or a declaration of the Examiner’s personal knowledge, to even suggest that these recited materials are known to be bioadhesives. Applicants thus submit that, in the rejection under 35 U.S.C. § 103(a), nothing has been provided in the Action or in Wang, the cited reference, to overcome the failure of the reference to teach, disclose, or suggest, two of the three required elements in claim 3. Accordingly, the Action has failed to establish a *prima facie* case for obviousness of claims 4 and 11 under Section 103(a).

### ***Summary***

From the above remarks, Applicants submit that Wang (\*379) fails to anticipate claims 3 and 12-15 of the instant application. Further, Applicants submit that a *prima facie* case for obviousness of claims 4 and 11 has not been established. Accordingly, Applicants respectfully request the withdrawal of these rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a).

Respectfully submitted,  
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